K073430

6. 510(k) Summary

Contact: Mr. Justin Eggleton
Musculoskeletal Clinical & Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
202.552.5800

Device Trade Name: Valeo™ Pedicle Screw System

Manufacturer: Amedica Corp.
615 Arapeen Drive, Suite 302
Salt Lake City, UT 84108

JAN 29 2008

Common Name: Pedicle screw spinal system

Classification: 21 CFR §888.3070

Class: III

Product Code: NKB, MNH, MNI

Indications For Use:

The Valeo™ Pedicle Screw System is intended for noncervical pedicle fixation and noncervical nonpedicle fixation as an adjunct to fusion for the following acute and chronic instabilities or deformities for the T1-S1 vertebrae in skeletally mature patients: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion.

Device Description:

The Valeo™ Pedicle Screw System comprises non-sterile, single use, titanium alloy components for creating a posterior spinal implant construct. The system attaches to the spine through a component system comprising screws, rods, connectors, and set screws. The system is designed to stabilize the spine during the fusion process. The Valeo Pedicle Screw System is fabricated from wrought Ti-6Al-4V (ISO 5832-3).

Predicate Device(s):

The Valeo™ Pedicle Screw System was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used. The cited references include:

- Jemo Spine Delta™ Spinal Fixation System (K071857)
- U&I Optima™ Spinal System (K031585)
- DePuy Expedium Spine System (K070387)
- Medtronic Sofamor Danek TSRH® Spinal System (K072317)
- Zimmer ST360°® Spinal Fixation System (K072183)
- Theken Spine Coral™ Spinal System (K070962)
- DePuy Spine VIPER Spine System (K071860)
- Vertebron PSS™ Pedicle Screw System (K071376)
- Custom Spine ISSYS LP Spinal Fixation System (K070281)
- EBI® Array® Spinal System (K062685)
- Globus Medical REVERE™ Stabilization System (K061202)
- Amedica Valeo™ Pedicle Screw System (K072022)

Performance Standards:

Testing performed indicates the Valeo™ Pedicle Screw System is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 2008

Amedica Corporation
% Musculoskeletal Clinical Regulatory Advisers, LLC
Mr. Justin Eggleton
1331 H Street Northwest, 12th Floor
Washington, DC 20005

Re: K073430
Trade/Device Name: Valeo™ Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH
Dated: December 5, 2007
Received: December 6, 2007

Dear Mr. Eggleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. Indications for Use

510(k) Number (if known): _____

Device Name: Valeo™ Pedicle Screw System

The Valeo™ Pedicle Screw System is intended for noncervical pedicle fixation and noncervical nonpedicle fixation as an adjunct to fusion for the following acute and chronic instabilities or deformities for the T1-S1 vertebrae in skeletally mature patients: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buelow

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073430